IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,	)	
Plaintiffs/Counter-Defendants	)	C.A. No. 07-333-SLR C.A. No. 07-348-SLR
v.	)	C.A. No. 07-409-SLR
JOHNSON & JOHNSON, INC. and CORDIS CORPORATION	)	**REDACTED PUBLIC VERSION**
Defendants/Counter-Plaintiffs	)	

DEFENDANTS/COUNTER-PLAINTIFFS JOHNSON & JOHNSON AND CORDIS CORPORATION'S OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE ASSERTED CLAIMS OF THE '7286, '3286, AND '473 PATENTS-IN-SUIT

Of Counsel:

David T. Pritikin
William H. Baumgartner, Jr.
Russell E. Cass
SIDLEY AUSTIN LLP
1 S. Dearborn Street
Chicago, Illinois 60603
(312) 853-7000

Bindu Donovan
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, New York 10019
(212) 839-5300

ASHBY & GEDDES
Steven J. Balick (I.D. #2114)
John G Day (I.D. #2403)
Lauren E. Maguire (I.D. #4261)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888

Attorneys for Defendants/Counter-Plaintiffs Johnson & Johnson and Cordis Corporation

Dated: October 9, 2009

TABLE OF CONTENTS

Page

NATURE AND STAGE OF THE PROCEEDINGS 1

SUMMARY OF THE ARGUMENT 1

STATEMENT OF FACTS 1

SUMMARY OF APPLICABLE LAW 3

ARGUMENT 4

I. If BSC's Proposed Constructions Are Rejected for the Four Claim Terms At Issue, BSC's Motion Is Moot. 4

II. Even If BSC's Proposed Claim Constructions Are Adopted, Disputed Issues of Fact Remain As To Whether the Promus Stent Meets All of the Limitations Identified by BSC, Either Literally or Under the Doctrine of Equivalents 4

A. "Biocompatible:" 4

1. Disputed Issues of Fact Remain As To Whether the Promus Stent Literally Satisfies BSC's Proposed Construction of "Biocompatible." 4

(a) The Testimony of Professor Mikos 5

(b) Positions Taken by Abbott before the FDA and European Regulatory Agencies 6

(c) Abbott's and BSC's Failure To Tell Regulatory Authorities, Medical Professionals, or Patients That the Xience/Promus Stent Causes a Negative Tissue Reaction. 7

2. Disputed Issues of Fact Also Exist Concerning Whether Promus Satisfies BSC's Proposed Construction of "Biocompatible" Under the Doctrine of Equivalents 8

B. "Coating…Applied Thereto" 11

C. Polymer 13

D. "Present in an Amount Effective to Inhibit Neointimal Proliferation" 15

III. The Court Does Not Have Jurisdiction over Claims 1, 2, 5, 6, 40, 41, 44, 47 and 48 of the '3286 Patent Because Cordis Has Given BSC a Covenant-Not-To-Sue. 17

CONCLUSION 18

TABLE OF AUTHORITIES

CASES **PAGE(S)**

AFG Indus., Inc. v. Cardinal IG Co.,
375 F.3d 1367 (Fed. Cir. 2004).....3

Amgen, Inc. v. Ariad Pharma., Inc.,
577 F. Supp. 2d 702 (D. Del. 2008).....17, 18

Anderson v. Liberty Lobby, Inc.,
477 U.S. 242 (1986).....3

Baxter Healthcare Corp. v. Spectramed, Inc.,
49 F.3d 1575 (Fed. Cir. 1995).....3

Benitec Australia, Ltd. v. Nucleonics, Inc.,
495 F.3d 1340 (Fed. Cir. 2007).....17

Cordis Corp. v. Boston Scientific Corp.,
561 F.3d 1319 (Fed. Cir. 2009).....9, 10

DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.,
469 F.3d 1005 (Fed. Cir. 2006).....9, 14

Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.,
149 F.3d 1309 (Fed. Cir. 1998).....9, 14

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.,
535 U.S. 722 (2002).....8

Freedman Seating Co. v. American Seating Co.,
420 F.3d 1350 (Fed. Cir. 2005).....9

Highway Equip. Co., Inc. v. FECO, Ltd.,
469 F.3d 1027 (Fed. Cir. 2006).....17

Izumi Prods. Co. v. Koninklijke Philips Elecs. N.V.,
315 F. Supp. 2d 589 (D. Del. 2004).....8

Jervis B. Webb Co. v. Southern Sys., Inc.,
742 F.2d 1388 (Fed. Cir. 1984).....17

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007).....17

Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.,
429 F.3d 1364 (Fed. Cir. 2005).....10

Primos, Inc. v. Hunter's Specialties, Inc.,
451 F.3d 841 (Fed. Cir. 2006).....9

Seal-Flex, Inc. v. Athletic Track and Court Const.,
172 F.3d 836 (Fed. Cir. 1999).....3

Super Sack Mfg. Corp. v. Chase Packaging Corp.,
57 F.3d 1054 (Fed. Cir. 1995).....17

TruePosition Inc. v. Andrew Corp.,
507 F. Supp. 2d 447 (D. Del. 2007).....3

Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,
520 U.S. 17 (1997).....3, 8

STATUTES

Declaratory Judgment Act, 28 U.S.C. § 2201.....17

NATURE AND STAGE OF THE PROCEEDINGS

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively, "BSC") brought these three declaratory judgment patent infringement cases. Johnson & Johnson and Cordis Corporation (collectively, "Cordis") counterclaimed for infringement of the three patents-in-suit: U.S. Patent No. 7,217,286 ("the '7286 patent"), U.S. Patent No. 7,223,286 ("the '3286 patent"), U.S. Patent No. 7,229,473 ("the '473 patent"). The Court has scheduled a claim construction and summary judgment hearing on October 30, 2009, a pretrial conference on January 14, 2010, and a trial beginning February 4, 2010.

SUMMARY OF THE ARGUMENT

BSC claims its Promus Everolimus-Eluting Coronary Stent System ("Promus") does not meet four limitations in the asserted claims of these patents: (1) "biocompatible;" (2) "coating...applied thereto;" (3) "polymer;" and (4) "present in an amount effective to inhibit neointimal proliferation." BSC concedes that if its proposed claim construction is not adopted for a particular claim term, it is not entitled to partial summary judgment of non-infringement for that limitation. But in any event, BSC's motion should be denied because, even if the Court adopts each of BSC's proposed constructions, disputed issues of fact remain as to whether Promus meets these limitations, either literally or under the doctrine of equivalents.

STATEMENT OF FACTS

Cordis claims that the Promus stent infringes the following claims of the patents-in-suit: Claims 1-5 of the '7286 patent; Claims 9, 10, 21, 25, 27, 28, 29, 30-39, 51, 52, 63, 67, 69, and 70-77 of the '3286 patent; and Claims 1-5 of the '473 patent.

Promus is a private-label version of the Xience V stent sold by Abbott.[1] (Mikos Decl. A5, ¶ 5.) Abbott manufactures Promus for BSC, and BSC has been selling Promus in the United States since receiving FDA approval in July 2008. (Id.)

Promus contains a polymer coating that releases the drug everolimus and consists of a poly n-butyl methacrylate ("PBMA") primer layer and an outer layer of poly vinylidene fluoride and hexafluoropropylene ("PVDF-HFP"). (Id.)

REDACTED

(Mikos Decl. A10-11, ¶¶27-29.)

The Promus stent received FDA approval following extensive clinical trials.

REDACTED (Mikos Decl. A4, ¶10.) In particular, the PBMA and PVDF-HFP polymers provide a biocompatible coating. They perform their function in the body with a clinically acceptable biological response, they do not elicit any unacceptable tissue reactions, and they do not promote the formation of mural thromboses.

REDACTED

(Mikos Decl. A4, ¶7.) When Promus is implanted in an artery, the everolimus stops most of the smooth muscle cells in the artery from proliferating. (Mikos Decl. A12, ¶33.) The Promus stent (like Cordis's pioneering Cypher® stent) therefore produces very low rates of restenosis (re-narrowing of the coronary artery) in the patients that receive it.

[1] Abbott sells the Promus stent under the name "Xience." Because Abbott designed and developed the Promus stent, and applied for regulatory approval to manufacture and sell the stent in the United States and overseas, many of the documents in this case refer to the Promus stent as Xience.

SUMMARY OF APPLICABLE LAW

To establish infringement, Cordis need only show, by a preponderance of the evidence, that BSC's Promus stent meets the asserted claims of the patents-in-suit, either literally or under the doctrine of equivalents. *See Seal-Flex, Inc. v. Athletic Track and Court Const.*, 172 F.3d 836, 842 (Fed. Cir. 1999). Literal infringement occurs when each limitation in the asserted claim is found in the accused device or process. *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1582 (Fed. Cir. 1995). Infringement under the doctrine of equivalents occurs when each limitation of a claim is practiced, either literally or by an equivalent. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-41 (1997).

In determining whether summary judgment is appropriate, the "evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Summary judgment must be denied if there is a genuine issue of material fact regarding whether the Promus stent infringes the patents-in-suit, either literally or under the doctrine of equivalents. *See, e.g., AFG Indus., Inc. v. Cardinal IG Co.*, 375 F.3d 1367, 1374 (Fed. Cir. 2004) (vacating grant of summary judgment because, at the very least, a genuine issue of material fact existed as to whether accused products infringed based upon analytical evidence, internal documents of the alleged infringer, and expert testimony); *TruePosition Inc. v. Andrew Corp.*, 507 F. Supp. 2d 447, 455-456 (D. Del. 2007) (J. Robinson) (denying motion for summary judgment of non-infringement because genuine issue of fact existed regarding whether the accused product practice a claim element based on expert testimony).

ARGUMENT

I. If BSC's Proposed Constructions Are Rejected for the Four Claim Terms At Issue, BSC's Motion Is Moot.

BSC's motion is predicated on the Court adopting its proposed construction for the four claim terms at issue. However, if BSC's proposed constructions are rejected for these claim terms, BSC's motion is moot.

II. Even If BSC's Proposed Claim Constructions Are Adopted, Disputed Issues of Fact Remain As To Whether the Promus Stent Meets All of the Limitations Identified by BSC, Either Literally or Under the Doctrine of Equivalents.

A. "Biocompatible:"

1. Disputed Issues of Fact Remain As To Whether the Promus Stent Literally Satisfies BSC's Proposed Construction of "Biocompatible."

Even if BSC's proposed construction of "biocompatible" were adopted, there is a disputed issue of fact as to whether Promus meets this limitation, either literally or under the doctrine of equivalents. BSC does not argue that Promus promotes mural thrombus formation and could hardly make a credible argument of this kind,

REDACTED

Rather, BSC's non-infringement argument rests entirely on whether Promus elicits a "negative tissue reaction." However, Cordis's experts have opined that Promus is safe, that any tissue reaction it elicits is acceptable, and therefore not negative, and that the Promus stent thus literally satisfies the "biocompatible" claim requirement, even as interpreted by BSC. (Mikos Decl. A4, ¶9.)

BSC, on the other hand, argues that *any* tissue reaction is negative and that Promus does not literally satisfy the biocompatibility limitation under the definition it proposes. But BSC has

not cited any evidence or produced any testimony from experts or lay witnesses suggesting that the tissue reaction elicited by the polymers on the Promus stent causes any adverse effect in patients or is in any way clinically unacceptable. Nor has BSC ever told the doctors who implant these stents, or the patients who receive them, that the polymers on the Promus stent elicits any "negative tissue reaction" that is in any way clinically unacceptable. BSC's argument leads to the nonsensical result that no stent would practice the claims since, as BSC admits, any "foreign object inserted into the body...causes some inflammation." (BSC's Opening Brief in Support of its Motion for Summary Judgment of Non-infringement of the Asserted Claims of the '662 Patent-in-Suit at 12 (Sept. 16, 2009).)

Whether some benign level of inflammation elicited by the polymers used on the Promus stent constitutes a "negative tissue reaction" is a disputed issue of fact for the jury to decide. If BSC's construction of "biocompatible" is adopted, Cordis will rely on the following evidence, among other things, to show that the Promus stent literally satisfies the biocompatible limitation: (a) the testimony of Cordis's expert, Professor Antonios Mikos, of Rice University; (b) the undisputed statements Abbott made to the FDA and the European regulatory authorities to gain approval to manufacture and sell the stent; and (c) what BSC did ***not*** tell doctors and patients about the Promus stent.

(a) The Testimony of Professor Mikos

Cordis's expert, Professor Antonios Mikos, has opined that any tissue reaction caused by Promus is clinically acceptable, and therefore not a negative tissue reaction. (Mikos Decl. A4, ¶9.) He has based his conclusion on preclinical and clinical studies and other evidence concerning the actual performance of the Promus stent in animals and humans. (Mikos Decl. A6-8, ¶¶ 12-17.) Preclinical safety studies performed and published by Abbott favorably compared the tissue reaction from the Xience stent with a bare metal stent ("ML Vision") which

did not contain a polymer coating. (Perkins, Laura E.L., Xience V Everolimus-Eluting Coronary Stent System: A Preclinical Assessment, *J of Interventional Cardiol* 2009; 22: (A1121-1133) at A1121, A1127.) The studies showed that the tissue reaction from Xience was within recognized safety limits, was acceptable for use in humans, and was therefore not negative.

(b) Positions Taken by Abbott Before the FDA and European Regulatory Agencies.

REDACTED

REDACTED

These statements by themselves create a disputed issue of fact as to whether the tissue reaction caused by the Promus stent is "negative."

(c) Abbott's and BSC's Failure To Tell Regulatory Authorities, Medical Professionals, or Patients That the Xience/Promus Stent Causes a Negative Tissue Reaction.

BSC has never told the regulatory authorities, medical professionals, or patients that the polymers used on the Promus stent cause a "negative tissue reaction" that could harm a patient. Its failure to do so raises a disputed issue of fact as to whether any inflammation is genuinely "negative," as BSC's proposed claim construction requires.

2. Disputed Issues of Fact Also Exist Concerning Whether Promus Satisfies BSC's Proposed Construction of "Biocompatible" Under the Doctrine of Equivalents.

Even if Cordis failed to prove literal infringement, there would still be disputed issues of fact under the doctrine of equivalents. The doctrine of equivalents exists because, "[i]f patents were always interpreted by their literal terms, their value would be greatly diminished. Insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could destroyed by simple acts of copying." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 723 (2002).

An element is "equivalent" if the differences between the element and the claim limitation are "insubstantial." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-41 (1997). "One test used to determine 'insubstantiality' is whether the element performs substantially the same function in substantially the same way to obtain substantially the same result as the claim limitation." *Izumi Prods. Co. v. Koninklijke Philips Elecs. N.V.*, 315 F. Supp. 2d 589, 599-600 (D. Del. 2004) (J. Robinson) (citation omitted). The determination of infringement under the doctrine of equivalents is highly fact intensive and therefore not easily amenable to summary judgment. *Id.*

If one assumes no literal infringement, Dr. Mikos has opined that the polymer coating on Promus is insubstantially different from the claimed "biocompatible" coating. (Mikos Decl. A8, ¶18.) The coatings perform substantially the same function (coating the stent and holding and controllably releasing the drug), in substantially the same way (providing a polymer which is acceptable for use in the coronary artery and that allows for diffusion and release of the drug), to achieve substantially the same result (a polymer-coated drug-eluting stent that can be used to treat restenosis without causing any significant harm to the patient). (Id.)

BSC argues that the doctrine of equivalents does not apply here because allowing "biocompatible" to cover equivalents "that elicit some discernable negative tissue reaction" would vitiate the limitation. But BSC's argument proves too much. It is always true in a doctrine of equivalents case that the limitation in question is not literally satisfied. Finding infringement always "vitiates" the limitation in this sense.

There is no set formula for determining whether a finding of equivalence would vitiate a claim limitation and thereby violate the all limitations rule. Rather, courts must consider the totality of the circumstances of each case and determine whether the alleged equivalent can be fairly characterized as an *insubstantial change* from the claimed subject matter without rendering the pertinent limitation meaningless. *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1359 (Fed. Cir. 2005) (emphasis added). In *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, the Federal Circuit found that a claim limitation was not vitiated where the accused device contained "a subtle difference in degree, not a clear, substantial difference or difference in kind." 149 F.3d 1309, 1321 (Fed. Cir. 1998). And the Federal Circuit, upholding a decision by this Court (in the Jang patent case), very recently articulated that vitiation applies "where the accused device contained *the antithesis* of the claimed structure." *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1330 (Fed. Cir. 2009).

In *Cordis*, BSC claimed that "circular arcs" on Cordis's Bx Velocity stent infringed a claim requiring "corners" consisting of angles formed by intersecting struts under the doctrine of equivalents. The Federal Circuit held that the circular arcs were not antithetical to the angular "corners" required by the claim even though they did not contain any angle, and thus the Court held that infringement under the doctrine of equivalents did not vitiate the limitation. *See also DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005 (Fed. Cir. 2006) (finding

that a "conically-shaped" structure did not vitiate a claimed "spherically-shaped" structure where the written description in the patent did not label other shapes "inferior"); *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841 (Fed. Cir. 2006) (finding that an animal call that included "a dome" did not vitiate a claim that recited "a plate"); *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 429 F.3d 1364 (Fed. Cir. 2005) (finding that a pharmaceutical composition that included "microcrystalline cellulose" did not vitiate a claim that recited "a suitable amount of a *saccharide* to inhibit hydrolysis" of the composition).

There is no practical difference between zero tissue reaction and a small degree of tissue reaction that is nonetheless clinically acceptable. A minor inflammation of this type is certainly not the *antithesis* of a stent that causes no inflammation. *See Cordis Corp.*, 561 F.3d at 1329. Therefore, if the tissue reaction here is small, the doctrine of vitiation is no impediment to finding liability under the doctrine of equivalents. How small the tissue reaction is is a disputed issue of fact.

BSC also argues that two sentences in the specification of the patents-in-suit give rise to an estoppel "which prohibits recourse to the doctrine of equivalents" regarding the "biocompatible" limitation. (BSC Br. at 18-19.) The sentences state that "the [stent] coating material should not contribute to any adverse response by the body (*i.e.*, should be non-thrombogenic, non-inflammatory, etc.). To date, the ideal coating material has not been developed for this application." ('3286, Col. 3, lines 53-58 (A1054).) But the reason the "ideal coating material" does not exist is that zero inflammation has not yet been achieved. Thus, to read this portion of the specification as requiring zero inflammation is absurd.[2]

[2] BSC also tries to conjure up support for its estoppel theory by pointing to statements made by Cordis's expert Dr. Mikos during the reexamination of the '7286 patent, in which Dr. Mikos noted that, at the time the inventions were made, researchers were concerned about the

B. "Coating...Applied Thereto"

BSC argues that the Promus stent does not include a "coating" which is "applied thereto" as required by various asserted claims of the '3286 patent and the '473 patent. BSC's proposed construction of "coating" is "a distinct covering layer of a particular composition." BSC's proposed construction of "applied thereto" is "brought into direct contact with the stent surface." Even if BSC's proposed constructions are adopted by the Court for each of these limitations, there are disputed issues of fact as to whether the Promus stent meets these limitations, either literally or under the doctrine of equivalents.

The Promus stent contains two polymer layers. (Mikos Decl. A3, ¶6.) These layers literally satisfy BSC's proposed construction of "coating" because each is a distinct covering layer of a particular composition: the PBMA primer layer is a distinct layer of PBMA, and the PVDF-HFP layer is a distinct covering layer of PVDF-HFP.

There are disputed issues of fact as to whether the PVDF-HFP polymer layer is "applied to" the Promus stent under BSC's proposed construction. BSC argues that "stent" should be construed as "a device for providing support for a lumen in the body." This construction does not require that the stent be wholly metallic. Professor Mikos has opined that the Promus stent literally satisfies the claim limitation under BSC's construction because the "stent" to which the PVDF-HFP polymer layer is applied includes both the underlying metal structure and the primer layer. (Mikos Decl. A9, ¶21.) Professor Mikos has pointed out that persons of ordinary skill in the art typically use the term "stent" to refer to the device, ***including*** the coating. (Mikos Decl.

---

possibility of polymer coatings causing inflammation. (BSC Br. at 19.) BSC appears to claim that, by characterizing the prior art as teaching the inflammatory nature of polymers, Cordis somehow disclaimed the use of polymers that cause ***any*** amount of inflammation, regardless of whether it has therapeutic significance. This misconstrues Dr. Mikos's declaration. Dr. Mikos was merely explaining that a polymer that produced an acceptable inflammatory response was needed, not that a polymer with ***no*** such response was needed.

A9, ¶22.) Both BSC and Abbott use the term "stent" in this manner. Abbott refers to the Xience "stent," even though the Xience stent includes a coating. (Id.) For example, an article published in 2009 by five Abbott employees involved in the design and development of the Xience stent is entitled "Xience V *Stent* Design and Rationale" even though the article concerns the entire Xience stent (including the polymer coating) – not just the architecture of the bare metal stent alone.[3] (See Ding, Ni (Nadine), Xience V Stent Design and Rationale, J of Interventional Cardiol. 2009; 22:S18-S27 (A1103-A1112) (emphasis added).) Indeed, Abbott states in its Patient Guide for Xience that the Xience stent has a "thin coating of everolimus on its surface." (Xience V Patient Information Guide at A2902.) Whether the PVDF-HFP polymer layer is "applied to" the Promus stent (even under BSC's proposed construction) is a disputed issue of fact that the jury must resolve.

Even assuming that there were no literal infringement because the PVDF-HFP layer does not contact the metal portion of the stent, there would remain a factual dispute as to whether the Promus stent satisfies this limitation under the doctrine of equivalents. Professor Mikos has opined that the application of the PVDF-HFP polymer to a thin PBMA primer layer on the metal portion of the stent would be insubstantially different from the application of the coating to the metal portion of the stent. (Mikos Decl. A10, ¶24.) Doing so performs substantially the same function (creating a stent capable of releasing a drug) in substantially the same way (coating the stent with a polymer capable of containing and releasing the drug in a controlled fashion) to achieve substantially the same result (a drug-eluting stent capable of being used to treat restenosis). (Id.)

3

REDACTED

BSC argues that applying the doctrine of equivalents here would vitiate the "coating applied thereto" limitation. But, again, BSC's argument proves too much. Applying the doctrine of equivalents would mean that infringement would be found even though the claim limitation was not literally satisfied. But that is true in any doctrine of equivalents case. Using a primer is not the *antithesis* of applying a coating to the stent, even under BSC's proposed construction. Professor Mikos has opined that what is important is that the polymer-drug mixture stay on the device and not flake off, and that adherence can be facilitated through the use of a primer or some other technique. (Id.) If anything, using a primer layer is furthering the aim of applying a coating to the stent, not employing the antithesis of a coating.

There is also a factual dispute as to whether these claim limitations could be met by the PBMA primer layer alone, which is applied directly to the metal portion of the Promus stent. BSC argues that the primer layer cannot meet the "coating" limitation

REDACTED

and, in certain asserted claims, the coating must comprise "a mixture of a biocompatible polymeric carrier and a therapeutic agent" (as required in Claim 1 of the '473 patent) or "a biocompatible polymer/drug mixture" (as required in Claim 1 of the '3286 patent).

REDACTED

Whether the PBMA layer meets these limitations is therefore a question of fact that must be resolved by the jury.

C. Polymer

BSC's proposed construction of "polymer" is a "a material composed of many repeating units of a single monomer" – a definition which excludes copolymers such as the PVDF-HFP coating on the Promus stent. However, even if this construction is adopted by the Court, BSC's motion for summary judgment must still be denied, because disputed issues of fact remain as to

whether the PVDF-HFP layer on Promus is equivalent to the claimed polymer or, alternatively, whether the "polymer" limitation is met by the PBMA primer layer (which is a homopolymer).

Professor Mikos has opined that the PVDF-HFP coating on the Promus stent would be insubstantially different from the use of a homopolymer coating – performing substantially the same function (coating the stent and holding and controllably releasing the drug) in substantially the same way (providing a polymer suitable for use on a stent that allows for diffusion and release of the drug) to achieve substantially the same result (a polymer-coated drug-eluting stent that can be used to treat restenosis). (Mikos Decl. A10, ¶25.)

BSC argues that the PVDF-HFP copolymer used on the Promus stent cannot be equivalent to its proposed construction of "polymer" (which is limited to homopolymers) because it would vitiate the limitation. But, unlike *DePuy Spine*, the specification here does not distinguish polymers and copolymers or assert that copolymers are inferior to polymers.

REDACTED and performs the same function as the claimed "polymer" (coating the stent and holding and controllably releasing the drug). **REDACTED**

This is precisely the sort of modification "in degree" and not "in kind" that does not result in a finding of vitiation. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1321 (Fed. Cir. 1998).

In the alternative, the PBMA layer itself literally satisfies the various "polymer" limitations in the asserted claims. PBMA is composed of many repeating units of a single monomer (butyl methacrylate) and therefore meets BSC's proposed construction of "polymer" (a material composed of many repeating units of a single monomer). (Mikos Decl. A10, ¶27.)

REDACTED

REDACTED

REDACTED

Whether Professor Mikos is correct or not is a disputed fact that the jury must resolve.

D. "Present in an Amount Effective to Inhibit Neointimal Proliferation"

BSC has proposed that "present in an amount effective to inhibit neointimal proliferation" should be construed to mean "an amount sufficient to stop" neointimal proliferation.

Even if BSC's proposed claim construction is adopted, a disputed issue of fact remains as to whether the Promus stent literally satisfies the limitation. Professor Mikos has opined that the Promus stent meets this limitation because, after implantation, the everolimus stops a sufficient amount of the smooth muscle cells in the neointima from proliferating to achieve a clinically effective treatment of restenosis. (Mikos Decl. A12, ¶33.)

REDACTED

Furthermore, even if one assumed that there was no literal infringement because the amount of everolimus on the Promus stent was not sufficient to stop all neointimal proliferation, there would still remain a fact question as to whether the Promus stent satisfies this limitation under the doctrine of equivalents. Dr. Mikos has opined that the everolimus on the Promus stent performs substantially the same function (inhibiting neointimal proliferation) in substantially the same way (binding to FKBP12 and mTOR to prevent cell replication in the G1 phase) to achieve substantially the same result (preventing restenosis) as a stent that stops all neointimal proliferation. (Mikos Decl. A12, ¶35.)

BSC argues that allowing this limitation to extend to stents which do not stop all neointimal proliferation would vitiate the limitation. But, again, BSC's argument proves too much. Applying the doctrine of equivalents would mean that infringement would be found even

though the claim limitation was not literally satisfied. But that is true in any doctrine of equivalents case. A very small amount of neointimal proliferation is not the antithesis of no neointimal proliferation. The two are insubstantially different.

III. The Court Does Not Have Jurisdiction over Claims 1, 2, 5, 6, 40, 41, 44, 47 and 48 of the '3286 Patent Because Cordis Has Given BSC a Covenant-Not-To-Sue.

BSC's declaratory judgment actions for non-infringement and invalidity of Claims 1, 2, 5, 6, 40, 41, 44, 47 and 48 of the '3286 patent are moot. Cordis notified BSC on June 16, 2009 that it did not intend to assert these claims and has granted BSC a covenant not to sue with regard to any claim that BSC's Promus stent infringes these claims.[4] (A1202-A1198.)

For there to be jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201, there must be "a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citations omitted). The "controversy" must exist at all stages of the case, not merely when the complaint was filed. *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1345 (Fed. Cir. 2007) (citations omitted). A covenant not to sue for infringement "eliminates jurisdiction with respect to remaining declaratory claims for patent invalidity and unenforceability." *Amgen, Inc. v. Ariad Pharma., Inc.*, 577 F. Supp. 2d 702, 709 (D. Del. 2008), *citing Highway Equip. Co., Inc. v. FECO, Ltd.*, 469 F.3d 1027, 1033 n.1 (Fed. Cir. 2006); *see also Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995). This issue is decided on a case by case bases. *Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984).)

[4] Cordis has also granted Abbott, BSC's supplier of the Promus stent, a covenant not to sue on those claims, eliminating any additional risk that BSC's supply of stents could be threatened by Cordis's pending lawsuit against Abbott in New Jersey. (A1199-A1201.)

Consistent with its posture in this case, on October 9, 2009, Cordis executed a covenant not to sue

REDACTED

(A1202-A1198.)

Boston Scientific's motions for summary judgment, as they relate to the validity of these claims, are therefore no longer justiciable and should be denied as moot. *See Amgen, Inc.*, 577 F. Supp. 2d at 712-13.

CONCLUSION

For the foregoing reasons, BSC's motion for summary judgment of non-infringement should be denied. BSC's motions for summary judgment, as they relate to Claims 1, 2, 5, 6, 40, 41, 44, 47 and 48 of the '3286 patent, are no longer justiciable and should be denied.

ASHBY & GEDDES

/s/ Lauren E. Maguire

Steven J. Balick (I.D. #2114)
John G Day (I.D. #2403)
Lauren E. Maguire (I.D. #4261)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

Attorneys for Defendants/Counter-Plaintiffs Johnson & Johnson and Cordis Corporation

Of Counsel:

David T. Pritikin
William H. Baumgartner, Jr.
Russell E. Cass
SIDLEY AUSTIN LLP
1 S. Dearborn Street
Chicago, Illinois 60603
(312) 853-7000

Bindu Donovan
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, New York 10019
(212) 839-5300

Dated: October 9, 2009

CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of October, 2009, the attached **REDACTED PUBLIC VERSION OF DEFENDANTS/COUNTER-PLAINTIFFS JOHNSON & JOHNSON AND CORDIS CORPORATION'S OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE ASSERTED CLAIMS OF THE '7286, '3286, AND '473 PATENTS-IN-SUIT** was served upon counsel of record at the address and in the manner indicated:

Josy W. Ingersoll, Esquire — VIA ELECTRONIC MAIL
Young Conaway Stargatt & Taylor
The Brandywine Building
1000 West Street
Wilmington, DE 19801

Richard L. DeLucia, Esquire — VIA ELECTRONIC MAIL
Kenyon & Kenyon
One Broadway
New York, NY 10004

Nicholas J. Nowak, Esquire — VIA ELECTRONIC MAIL
Kenyon & Kenyon
1500 K Street N.W., Suite 700
Washington, DC 20036

James F. Hibey, Esquire — VIA ELECTRONIC MAIL
Howrey LLP
1299 Pennsylvania Ave., NW
Washington, DC 20004

Robert E. McAlhany, Jr., Esquire — VIA ELECTRONIC MAIL
Howrey LLP
1950 University Avenue, 4th Floor
East Palo Alto, CA 94303

Kate Berezutskaya, Esquire
Howrey LLP
321 North Clark Street
Suite 3400
Chicago, IL 60654

VIA ELECTRONIC MAIL

/s/ John G. Day

John G. Day